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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,514	BELLY ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Remark

Claims 7-22 have been canceled.

Claims 1-6 are pending and are under prosecution therefore.

The present Office Action contains at least one objection and/or rejection not necessitated by amendment and is therefore made **Non-Final**.

Information Disclosure Statement

On page 6 of the response, Applicants state that corrected IDS as a separate mailing will provided in response to the Office Action mailed on June 20, 2005, communicating that the IDS received on March 2, 2005 was non-compliant.

To date of the present Office communication, IDS has not been received.

Claim Interpretation

The term, "about" is defined as a variance of 110% of the noted values (page 13, lines 9-10). With regard to the term, "about," being associated with pH, the term is defined as +/- 0.5 pH unit (page 13, lines 10-11).

Specification

The objection to the specification made in the Office Action mailed on June 20, 2005 is withdrawn in view of a careful reconsideration of the application.

Claim Rejections - 35 USC § 112

The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on June 20, 2005 is withdrawn in view of the Amendment received on December 22, 2005.

Rejection, New Grounds

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for reciting the phrase, "contacting said precipitate with a base to raise the solution pH," because there is insufficient antecedent basis for the limitation, "the solution." For the purpose of prosecution, the phrase has been construed to mean, "the buffer pH."

Claim 1 is indefinite for reciting the term, "polymer comprised of recurring units," because it is unclear what unit is being recurring.

Claims 2-6 are indefinite by way of their dependency on claim 1.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for providing a nucleic acid from a sample not previously treated with a cell lysing reagent via treatment of said sample with a weakly basic polymer wherein said sample comprises mammalian cells, does not reasonably provide enablement for a method for providing a nucleic acid from a sample not previously treated with a cell lysing reagent via treatment of said sample with a weakly basic polymer wherein said sample comprises non-mammalian cells (such as

plants or bacteria). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in In Re Wands (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

The Nature of the Invention & Breadth of the Claims:

The nature of the invention relates to a method of extracting/isolating nucleic acid from a sample via treatment with weakly basic polymer comprised of recurring units derived by addition polymerization of series of ethylenically unsaturated polymeriziable monomers, wherein the sample is not previously treated with a cell lysing reagent.

While the nature of the "sample" is not specifically limiting[1], the breath of the claims embrace a method which pertains isolating nucleic acid from a sample comprising cells, the types of cell which are not limited in any way, wherein nucleic acids are isolated from said cells by treatment with said weakly basic polymer, said cells not prior treated with a lysing reagent.

The issue of the enablement is whether the invention as claimed based on the specification and in view of prior art would enable a skilled artisan of the pertinent field to practice the invention fully commensurate in scope of the claims – i.e., samples which are non-mammalian cells.

[1] A "sample" without further limitation in the claims in view of the absence of an explicit definition of the instant specification does not preclude a stock DNA solution.

The Amount of direction & Working Examples:

All of the examples disclosed by the instant specification are directed to sample which are of mammalian species. The specification discloses the isolation of nucleic acid via claimed method wherein the sample is white blood cells (page 37, line 30 through page 37). The specification on pages 38-39 discloses that some DNA were isolated by the claimed method without first lysing the white blood cells (see Table IV on page 39). On pages 40 and 44, the specification discloses that nucleic acids were isolated by the claimed method from a sample, wherein said sample is serum or plasma. Table VI (on page 43) and Table VII (on page 45) show the results of the nucleic acid yield produced from the claimed method.

The instant specification does not have any guidance in practicing the method wherein the sample is non-mammalian.

State of Prior art & Unpredictability:

Manen et al. (BMC Plant Biology, 2005, vol. 5, no. 23, pages 1-9), disclose the fundamental differences between mammalian cells and plant cells and the difficulties associated with extracting nucleic acids therefrom.

> "DNA extraction from plant tissues, unlike DNA isolation from mammalian tissues, remains difficult due to the presence of rigid cell wall surrounding the plant cells. Currently used methods inevitably require a laborious mechanical grinding step, necessary to disrupt the cell wall for the release of DNA." (page 1, 1st column, 1st paragraph)
> The artisans continue:
>
> "Whereas animal tissues need only a lysis buffer containing detergents and proteinase K to release their DNA, plant tissues need in addition to a mixture of carbohydrase enzymes able to digest cell wall." (page 3, 1st column, 1st paragraph)

For nucleic acids to be extracted from cell samples, the cell must first be ruptured in order to release the nucleic acids. The artisans clearly demonstrate the difficulties associated with rupturing plant cells having cell walls, for the purpose of releasing nucleic acids therefrom.

Gwynne et al., in their article titled, "Drug Discovery and Biotechnology Trends Genomes and Microbes: Resisting Drug Resistance," published in sciencemag.org on May 9, 2003, also express the differences and difficulties associated with rupturing the cell walls of bacteria:

> "Bacteria are more difficult than mammalian cells; sometimes, plant bacteria are double walled, the space between the walls is air, and their membranes tend to be thicker than those of mammalian cells." (page 4 of the print out; 4th paragraph).

The claimed invention requires that the sample comprising the nucleic acid must not be first lysed via use of a lysing reagent. Hence, it is implicitly required that the claimed weakly basic polymer rupture the cell so as to first release then bind the nucleic acids.

Based on the fact that plant and bacteria cells are clearly more difficult to rupture, and in the absence of such example and guidance, it remains unpredictable whether the claimed method would be enabled for extracting nucleic acid from these non-mammalian cells.

Skill level & Amount of experimentation:

While the skill level of the artisan in question is deemed high, based on the lack of teachings in both the instant specification and in the prior art, coupled with well-known differences between non-mammalian cells and mammalian cells and the difficulties associated with rupturing non-mammalian cells, one of skill in the art would not be able to practice the invention fully commensurate in scope of the claims for the reasons provided above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Backus et al. (U.S. Patent No. 5,582,988, issued December 10, 1996), made in the Office Action mailed on June 20, 2005 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on December 22, 2005 have been fully considered but they are not found persuasive.

Applicants' arguments are addressed in the same order they were presented in the "Response to Arguments" section.

The Rejection:

The method disclosed by Backus et al. provides a sample, wherein on column 19, beginning at line 59, the artisans disclose that the sample is calf thymus DNA. The steps employed in capture and release of this DNA sample has not been subject to prior treatment with a cell lysing reagent.

Particularly, Backus et al. disclose a method of providing a nucleic acid from a sample, comprising the steps of:

A) at a pH of less than 7, contacting the sample suspected of containing a target nucleic acid with a water-soluble, weakly basic polymer in an amount sufficient to form a water-insoluble precipitate of the weakly basic polymer with all nucleic acids present in the sample, including the target nucleic acid (column 2, lines 20-24);

B) separating the water-insoluble precipitate from the sample, (column 2, lines 25-26) and

C) contacting the precipitate with a base to raise the solution pH to greater than 7, and thereby releasing the nucleic acids, including the target nucleic acid, from the weakly basic polymer (column 2, lines 27-30),

The weakly basic polymer comprising recurring units derived by addition polymerization of one or more ethylenically unsaturated polymerizable monomers having an amine group which can be protonated at acidic pH (column 2, liens 30-35).

With regard to the certain weight percentages of the monomers added to produce the "weakly basic" polymer, such is a product produced by the process and as the weakly basic polymer of the Backus et al. achieves the identical result, the products are determined to the same.

With regard to claim 2, Backus et al. disclose that the pH of the solution containing the released nucleic acid could be adjusted from about 6 to about 9 (column 5, lines 45).

With regard to claim 3, the base is disclosed as being, for example, sodium hydroxide (column 5, lines 13-22).

With regard to claim 4, Backus et al. disclose that the weakly basic polymer used in an amount from 0.01 to about 0.5% weight (column 4, lines 48-51).

With regard to claim 5, a weak base is accompanied by heating of about 50° to about 125° (column 5, lines 23-27).

With regard to claim 6, strong base is used without heating in releasing the target nucleic acid from the weakly basic polymer (column 5, lines 40-45).

Therefore, the invention as claimed is clearly anticipated by Backus et al.

Response to Arguments:

Applicants contend that the claimed method is different from that which is disclosed by Backus et al. Applicants' contention appears to be based on the claim amendment which has been amended to recite that a method now involves a sample "not previously treated with a cell lysing reagent..."

While the limitation clarifies and distinguishes the invention from an embodiment of disclosure disclosed by Backus et al., another embodiment of the disclosure fully anticipates the claimed invention for the following reasons.

The claims, even as amended recites that the method is drawn to that which employs a "sample" not previously treated with a cell lysing reagent. The claims do not recite what is considered as a sample nor does the instant specification provide an explicit (not exemplary) definition with regard to what is considered to be a "sample."

As recited and pointed to above, Backus et al. disclose another embodiment of their invention wherein the artisan demonstrate capture and release of nucleic acids, wherein the "sample" is calf thymus DNA solution (see column 19, lines 54-67; column 20, lines 14-15). This disclosure is clear that no previous treatment with cell lysing reagent had been performed.

The present interpretation appears to be consistent with the claimed invention as even the instant application discloses that their invention employs the same calf thymus DNA solution in their working example of the invention (see page 35, beginning at line 5).

Finally, on page 13 of the Response, Applicants point to column 16, lines 15-65 of the Backus patent for stating that a lysis step is employed.

The cited portion of the Backus patent is drawn to preparation of copolymers and does not have any disclosure drawn toward lysis as asserted by Applicants.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
Art Unit 1637
2/27/2006

YOUNG J. KIM
PATENT EXAMINER

yjk